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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|--------------------------------|------------------------|
| 09/963,347 | 09/25/2001 | J. Fernando Bazan | DX0903K1 | 9754 |
| 24265 7590 08/28/2007 SCHERING-PLOUGH CORPORATION PATENT DEPARTMENT (K-6-1, 1990) 2000 GALLOPING HILL ROAD KENILWORTH, NJ 07033-0530 | | | EXAMINER CHERNYSHEV, OLGA N | |
| | | | ART UNIT 1649 | PAPER NUMBER |
| | | | MAIL DATE 08/28/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/963,347 | BAZAN ET AL. | |
| | Examiner | Art Unit | |
| | Olga N. Chernyshev | 1649 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/19/7</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claim 33 is pending and under examination in the instant office action.
2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
3. Applicant's arguments filed on June 19, 2007 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 33 stands rejected under 35 U.S.C. 102(e) as being anticipated by Sims et al. (US Patent 6, 555, 520, April 29, 2003, filed May 9, 2001) for those reasons of record in section 6 of Paper mailed on December 19, 2006 and earlier in 5 of Paper mailed on May 11, 2006, section 7 of Paper mailed on October 14, 2005, section 11 of Paper mailed on December 08, 2003 and in section 8 of Paper mailed on August 02, 2004.

Briefly, claim 33 is directed to an isolated polypeptide encoded by a nucleic acid of SEQ ID NO: 1 ("IL-B50" polypeptides). Sims et al. document discloses polynucleotide sequences that have 100% identity to the instant SEQ ID NO: 1, thus fully anticipating the instant claim 33.

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Because the specific, substantial and credible utility of the instant IL-B50 polypeptides, which supports the enablement of IL-B50 polypeptides is only disclosed in the instant application, the effective filing date for the instant invention is determined as the filing date of the instant application (09/25/2001), which makes patent of Sims et al. a proper 102(e) reference.

Applicant traverses the rejection on the premises that the instant IL-B50 has structural similarity to the known polypeptide IL-7 and that the provisional application filed in 1998 states that “[I]t is likely that IL-B50 has either stimulatory or inhibitory effects on hematopoietic cells”, therefore, Patent of Sims et al. is not a proper 102(e) art (pp. 2 and 3 of the Response). Applicant further refers to the Declaration of Dr. Sali to support this argument. This argument has been given careful consideration but it is unpersuasive that the specific and substantial credible utility of the instant claimed polypeptides was disclosed in the earlier provisional application.

The Declaration of Andrej Sali under 37 CFR 1.132 filed on June 19, 2007 is insufficient to overcome the rejection of claim 33 based upon 101/112, first paragraph as set forth in the last Office action for reasons set forth below.

The declaration of Dr. Sali states that 1) the structural sequence similarity between IL-7 and the instant claimed IL-B50 is statistically significant (conclusion at section 13), and 2) based on that statistically significant similarity, “a person of skill in the art would have considered the statement relating the ability of IL-B50 to stimulate or inhibit T cells and B cells to be credible” (section 5). However, the Examiner has never disputed that the similarity between IL-7 and IL-B50 is of statistical significance; the issue at hand is that the similarity between these molecule is only 28.1%. Based on this limited degree of similarity, one of skill in the art would reasonably conclude that the disclosed protein would probably have some effect, “stimulatory or inhibitory”

rather than no effect at all, on certain cells. However, in order to discover how to use the instant polypeptides, a skilled practitioner would have to perform significant amount of further research to discover what is, if any that particular effect that IL-B50 shares with IL-7. Thus, at the time of filing, to employ the polypeptide of the instant invention in any of the disclosed methods would clearly be using it as the object of further research which has been determined by the courts to be a utility which, alone, does not support patentability.

The U.S. Court of Appeals for the Federal Circuit recently addressed the utility requirement in the context of a claim to DNA. *See In re Fisher*, 2005 WL 2139421 (Sept. 7, 2005). The *Fisher* court interpreted *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (1966), as rejecting a “de minimis view of utility” 2005 WL 2139421, at *4. The *Fisher* court held that § 101 requires a utility that is both substantial and specific. *Id.* At *5. The court held that disclosing a substantial utility means “show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some future date after further research. Simply put, to satisfy the ‘substantial’ utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public.” *Id.*

Just as in *Fisher* case where the Board reasoned that use of the claimed ESTs for the identification of polymorphisms is not a specific and substantial utility because “[w]ithout knowing any further information in regard to the gene represented by an EST, as here, detection of the presence or absence of a polymorphism provides the barest information in regard to genetic heritage,” (*Id.*, slip op. at 15), in the instant case, the disclosure of the structure of the polypeptide alone and assertion that it would probably either inhibit or stimulate activity of certain cell types solely based on a limited, 28.1% sequence similarity to another polypeptide

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with diverse spectrum of functions, provides for assertion of a use which is so vague that it is meaningless.

6. Thus, because '492 application did not disclose how to use the instant claimed invention, the priority of the filing date of that application as well as to both provisional applications (60/131,298 and 60/101,318) was denied, see MPEP 201.11 (U.S.C. 120 states that the disclosure of the invention in the prior application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112).

7. The instant application presented disclosure of new data obtained after the filing of the previous applications (see pp.64-69), which constitutes a CIP status of the instant application. With respect to the priority date, MPEP 706.02(a) makes it clear that

“(B) If the application is a continuation-in-part of an earlier U.S. application or international application, any claims in the new application not supported by the specification and claims of the parent application have an effective filing date equal to the filing date of the new application.

As such, because the instant invention is only fully enabled in the instant specification, the effective filing date of the instant invention is awarded as the filing date of the instant application, 09/25/2001, which makes Sims et al. document a proper prior art under 102(e).

Conclusion

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Y. Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

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like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Olga N. Chernyshev, Ph.D.
Primary Examiner
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August 21, 2007